ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3084.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 17, 1990 (55 FR 29106), FDA announced that a food additive petition (FAP 7B4012) had been filed by Yasuhara Chemical Co., Ltd., 1080 Takagi-cho Fuchu-city, Hiroshima 726 Japan. The petition proposed that the food additive regulations be amended to provide for the safe use of hydrogenated dipentene resin for use as a component of adhesives and coatings, hydrogenated dipentene-styrene copolymer resin for use as a component of adhesives, and hydrogenated-*beta*-pinene-*alpha*-pinene-dipentene copolymer resin for use as a component of adhesives and coatings intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive uses are safe, and that § 175.105 *Adhesives* (21 CFR 175.105) and § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) of the food additive regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 25, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 175.105 is amended in paragraph (c)(5) by alphabetically adding three new entries to the table to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * * * *	
Hydrogenated dipentene resin (CAS Reg. No. 106168–39–2).	
Hydrogenated dipentene-styrene copolymer resin (CAS Reg. No. 106168–36–9).	
Hydrogenated-*beta*-pinene-*alpha*-pinene-dipentene copolymer resin (CAS Reg. No. 106168–37–0).	

3. Section 175.300 is amended in paragraph (b)(3)(xi) by alphabetically adding the following new entries to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(b) * * *

(3) * * *

(xi) * * *

* * * * *	
Hydrogenated dipentene resin (CAS Reg. No. 106168–39–2).	For use only with coatings in contact with acidic and aqueous foods.
Hydrogenated-*beta*-pinene-*alpha*-pinene-dipentene copolymer resin (CAS Reg. No. 106168–37–0).	For use only with coatings in contact with acidic and aqueous foods.

* * * * *

Dated: September 14, 1995.

I. Kaye Wachsmuth,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–23599 Filed 9–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 95F–0149]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester as an antioxidant and/or stabilizer in olefin polymers intended for use in contact with food. This action is in response to a petition filed by General Electric Co.

DATES: Effective September 25, 1995; written objections and requests for a hearing by October 25, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 21, 1995 (60 FR 32329), FDA announced that a food additive petition (FAP 5B4463) had been filed by General Electric Co., 501 Avery St., Parkersburg, WV 26102–1868. The petition proposed that the food additive regulations be amended in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester as an antioxidant and/or stabilizer in olefin polymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, and that the regulations in § 178.2010 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 25, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester (CAS Reg. No. 161717–32–4).	For use only at levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, and items 2.1, 2.2, or 2.3 (where the density of these polymers is not less than 0.94 gram per cubic centimeter), and items 3.1 or 3.2, provide that the finished polymer contacts food only of types I, II, and VI–B as described in Table 1 of § 176.170(c) of this chapter only under conditions of use B, C, D, E, F, G, and H as described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: September 15, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–23598 Filed 9–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ketamine Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Fermenta Animal Health Co. The ANADA provides for intramuscular use of ketamine hydrochloride injection in cats for restraint and to produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation and in nonhuman primates for restraint.

EFFECTIVE DATE: September 25, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Fermenta Animal Health Co., P.O. Box 338, 15th and Oak Sts., Elwood, KS 66024, filed ANADA 200–029, which provides for intramuscular use of ketamine hydrochloride injection (equivalent to 100 milligrams/milliliter (mg/mL) ketamine) in cats for restraint and to produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation and in nonhuman primates for restraint. The drug is limited to use by or on the order of a licensed veterinarian.

Fermenta Animal Health's ANADA 200–029 for ketamine hydrochloride injection (equivalent to 100 mg/mL ketamine) is approved as a generic copy of Fort Dodge Laboratories' NADA 045–290 for Vetalar® /Ketaset® (ketamine hydrochloride injection equivalent to 100 mg/mL ketamine). The ANADA is approved as of August 16, 1995, and the regulations are amended in 21 CFR 522.1222a(c) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 522.1222a is amended by removing and reserving paragraphs (a) and (d).

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20855, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1222a is amended by removing and reserving paragraphs (a) and (d), and by revising paragraph (c) to read as follows:

§ 522.1222a Ketamine hydrochloride injection.

(a) [Reserved]

* * * * *

(c) *Sponsors.* See Nos. 000856, 045984, 054273, and 057319 in § 510.600(c) of this chapter.

(d) [Reserved]

* * * * *

Dated: September 8, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23600 Filed 9–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Melarsomine Dihydrochloride for Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Rhone Merieux, Inc. The NADA provides for intramuscular use of injectable melarsomine dihydrochloride for the treatment of heartworm disease in dogs.

EFFECTIVE DATE: September 25, 1995.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0137.

SUPPLEMENTARY INFORMATION: Rhone Merieux, Inc., 7101 College Blvd., suite 610, Overland Park, KS 66210, filed NADA 141–042 to provide for intramuscular use of the injectable drug product Immiticide Sterile Powder which consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride to be reconstituted with the provided 2 milliliters of sterile water. The drug is indicated for the treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L_5) to mature adult infections of *Dirofilaria immitis* in dogs. The drug product is available by prescription. The NADA is approved as of July 21, 1995, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.1362 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning July 21, 1995, because no active ingredient